

REMARKSElection

In the previous Response to Office Action, Species I had been elected, where Species I is shown in Figures 1-2. The restriction requirement with regard to newly-identified Species III had been traversed. The Office Action indicated that the traverse was found persuasive. Thus, it is understood that only Species I and II are present in the application, and that Species I, as shown in Figures 1-2, has been elected.

Acknowledgement that claim 17 is generic is requested. The Office Action identifies claim 1 as generic. Claim 17 is also generic, because the claimed "auger" can be the conical spike of Species I or the fluted, screw-like element of Species II.

Information Disclosure Statement

The Examiner initialed the reference in the Information Disclosure Statement of May 27, 2005 entitled "'Cardica PAS-PORT Proximal Anastomosis System 510(k),' Section VI.C., 'Substantial Equivalence,' and Attachment 7 (unpublished)," (the "Reference") meaning that the Examiner has considered the reference pursuant to MPEP 609. This Reference was furnished in accordance with *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services Ltd.*, 394 F.3d 1348, 73 U.S.P.Q.2D 1593 (Fed. Cir. 2005) in order to make the Examiner aware of a portion of Cardica's 510(k) application to the Food and Drug Administration, regardless of the date of any of its specific contents.

The document that the Office Action identifies as the "St. Jude Medical Instructions for Use" is a part of the Reference, which the Examiner has already initialed as considered. Specifically, it is Attachment 7 of the Reference. The date of publication of this document is unknown. The Instructions for Use for a medical device are typically made available to users when the device is first tested, and European trials of the St. Jude Symmetry medical device

appear to have commenced at least as early as August 2000. Thus, the document that the Office Action identifies as the "St. Jude Medical Instructions for Use" is likely dated on or around August 2000. That Reference has been listed again for the Examiner's further consideration in the Form PTO-1449 submitted with this paper.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 1-6, 8-14

Applicants respectfully traverse the rejection of these claims.

Claim 1 claims "[a] tool for making an incision in and removing tissue from a vessel wall, comprising: a cutter; and a piercing member positioned within said cutter, wherein said piercing member and said cutter are configured to translate together to penetrate the wall of the vessel." (emphasis added)

U.S. Pat. No. 3,825,362 to Hougen ("Hougen") does not expressly or inherently describe each and every element of claim 1. Hougen discloses a pointed pilot pin 42 coaxial with an annular hole cutter 14. (Hougen; *e.g.*, col. 2, lines 36-37, 59-62; Figures 2-4, 6-15). The pilot pin 42 translates independently from the cutter 14: "[a]s the arbor advances axially toward the workpiece pilot pin 42 progressively retracts as cutter 14 advances into the workpiece." (Hougen; col. 3, line 67 through col. 4, line 2; *e.g.*, Figures 2-3, 12-14). After the cutter 14 cuts a slug 78 from the workpiece, the cutter 14 holds the slot 78 and retracts

relative to the pilot pin 42, and as a result the pilot pin 42 ejects the slot 78 from the cutter 14. (Hougen; col. 4, lines 24-37; Figures 3-4).

In contrast, claim 1 requires "a cutter; and a piercing member positioned within said cutter, wherein said piercing member and said cutter are configured to translate together to penetrate the wall of the vessel." (emphasis added). The corkscrew and cutting device of Hougen do not and cannot "translate together," as pointed out in the paragraph above. Rather, Hougen can only perform its "primary object" of "positively ejecting the round slug formed by the cutter" by the relative translational motion of the pilot pin 42 and the cutter 14. (Hougen; col. 2, lines 32-35). Thus, Hougen neither expressly nor inherently describes each and every element claimed in claim 1, and as a result claim 1 is believed to be in condition for allowance.

Further, claim 1 is directed to a surgical tool, and requires that "said piercing member and said cutter are configured to translate together to penetrate the wall of the vessel" that is identified in the preamble. However, the device of Hougen is a "machine tool" that is used to make holes in "conduit, a vehicle frame or body member, etc." (Hougen; col. 1, lines 63-65; col. 2, lines 50-51). As a result, Hougen discloses nothing about a piercing member and cutter that are configured to translate together to penetrate the wall of a vessel.

Claim 1 was acknowledged as generic in the Office Action of August 24, 2005, so allowance of generic claim 1 would be as to all species. Claims 2-6 and 8-14 depend from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 17-31, 33-39 and 51

Applicants respectfully traverse the rejection of these claims.

Claim 17 claims "[a] surgical tool for removing tissue from the wall of a vessel to

create an opening, comprising: a rotatable cutter; an auger assembly fixed to and substantially coaxial with said cutter, said auger assembly comprising an auger at its distal end; an actuator connected to at least one of said auger assembly and said cutter.” (emphasis added).

In contrast, the pilot pin 42 and cutter 14 of Hougen neither expressly nor inherently describes an auger assembly fixed to a cutter. Rather, as set forth above with regard to claim 1, the pilot pin 42 and cutter 14 of Hougen are movable relative to one another, and as a result are not and cannot be considered to be “fixed” relative to one another. Thus, Hougen neither expressly nor inherently describes each and every element claimed in claim 17, and as a result claim 17 is believed to be in condition for allowance.

Claim 17 is believed to be generic, because the claimed “auger” can be the conical spike of Species I or the fluted, screw-like element of Species II.. It is requested that claim 17 is acknowledged as generic. Claims 18-31, 33-39 and 51 depend from claim 17, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to claim 30, Hougen fails to disclose the claimed seal housing. The Office Action analogizes the seal housing to reference number 28 of Hougen. However, reference number 28 of Hougen identifies a yoke 28. (Hougen; *e.g.*, col. 2, lines 43-46; Figure 1). The yoke 28 includes a U-shaped opening 30, which is characterized in the OA as analogous to the “tip/guide”. (Hougen; *e.g.*, col. 2, lines 43-46; Figure 1). These characterizations are expressly disagreed with and not accepted. The claimed seal housing differs substantially from the flat U-shaped member of Hougen. “The seal housing 34 is a substantially hollow structure into which the proximal end of the auger assembly 10 extends.” (Application; page 12, lines 17-19; Figure 1). Further, “[t]he seal housing 34 includes an opening 36 at or near its distal end through which the introducer tip 28 and the auger assembly 10 extend,” and may include an opening at its proximal end as well. (Application; page 12, lines 19-25). The flat U-shaped member of Hougen bears no resemblance to a

“substantially hollow structure” having two ends and an opening through at least its distal end. Thus, Hougen does not and cannot expressly or inherently describe the claimed seal housing.

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claims 7, 15

Dependent claim 7 and 15 depend from claim 1, which is believed to be in condition for allowance, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 7 and 15 were rejected based on the reasoning that modification of the blade of Hougen is a “design choice.” (Office Action, page 3). However, “design choice” is not a ground for rejection under 35 U.S.C. §103. Design choices are discussed in the Manual of Patent Examining Procedure at MPEP 2144.04(VI)(C), but only insofar as they constitute a “rearrangement of parts.” Claim 7 cannot be a rearrangement of parts, because Hougen fails to disclose all of the elements of claim 7, particularly the claimed “distal end of said cutter [being] beveled outward.” Further, claim 15 cannot be a rearrangement of parts, because

Haugen fails to disclose all of the elements of claim 15, particularly the claimed "width of the proximal end of said spike [being] greater than the width of said shaft."

Claim 32

Dependent claim 32 depends from claim 17, which is believed to be in condition for allowance, and is thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claim 32 was rejected on the ground that "it would be obvious that tip 30 can be expandable to make the opening bigger." (Office Action, page 4). No rationale or reasoning is provided as to why making the introducer tip expandable would be obvious. Such reasoning must be provided under the Administrative Procedure Act (5 U.S.C. § 706) for the claim rejection to be valid. (*see Dickinson v. Zurko*, 1999 U.S. Lexis 4004, *24; 527 U.S. 150 (1999) (*citing SEC v. Chenery Corp.*, 318 U.S. 80, 89-93(1943)).)

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



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